APR 5 2000

K000534

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576-3544

Contact person: Kay A. Taylor

Date prepared: March 28, 2000

Predicate device

The Cobas® Integra Reagent Cassette for Rheumatoid Factors II is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Cobas® Integra Reagent Cassette for Rheumatoid Factor (K963292).

Device name

Proprietary name: Integra Reagent Cassette for Rheumatoid Factors II

Common name: Rheumatoid Factor Immunoassay

Classification name: System, Test, Rheumatoid Factor

Device description

The device is an immunoturbidimetric test for the quantitative determination of rheumatoid factor in serum and plasma for use on the Cobas® Integra family of analyzers.

510(k) Summary, continued

Intended use

For the quantitative immunological determination of human rheumatoid factors in serum and plasma.

Indication for use

The quantification of rheumatoid factor can be used as an aid in the diagnosis, prognosis, and monitoring of rheumatoid arthritis.

Substantial equivalence

The Cobas® Integra Reagent Cassette for Rheumatoid Factors II is equivalent to other devices legally marketed in the United States. We claim equivalence to the Cobas® Integra Reagent Cassette for Rheumatoid Factor (K963292).

Substantial equivalence – similarities

The following table compares the Cobas® Integra Reagent Cassette for Rheumatoid Factors II with the predicate device.

Feature	Modified Device (Integra RF II)	Predicate Device (Integra RF)
Intended use	For the quantitative immunological determination of human rheumatoid factors.	For the quantitative immunological determination of human rheumatoid factors.
Indication for use	Measurement of rheumatoid factor may be used as an aid in the diagnosis of rheumatoid arthritis.	For the quantitative immunological determination of human rheumatoid factors
Methodology	Immunoturbidimetric	Immunoturbidimetric
Storage & Stability	On board in use at +8°C = 8 weeks	On board in use at +8°C = 8 weeks
Control	RF/ASO T Control II (0758493)	RF/ASO T Control II (0758493)

Substantial equivalence – differences

The following table compares the Cobas® Integra Reagent Cassette for Rheumatoid Factors II with the predicate device.

Feature	Modified Device (Integra RF II)	Predicate Device (Integra RF)
Specimen	Serum and plasma	Serum
Instrument	Integra 700, Integra 400	Integra 700
Wavelength	583nm	552nm
Measuring range	• 0-120 IU/ml • with post-dilution 0-600 IU/ml	• 10-120 IU/ml • with post-dilution 10-600 IU/ml
Sample tubes	EDTA, Heparin and Citrate	Serum only
Calibrator	Preciset RF (2172828)	RF T Standard II (0758507)
Calibration Interval	• Each lot • 180 days	• Each lot • 28 days
R1	Polyanethole sulfonic acid in glycine buffer with bovine serum albumin stabilized with 0.09% sodium azide (liquid)	Polyethylene glycol (PEG) in glycine buffer with bovine serum albumin stabilized with 0.09% sodium azide (liquid)
R2	Latex particles coated with human IgG in glycine buffer stabilized with 0.09% sodium azide (liquid)	Latex particles coated with human IgG in glycine buffer stabilized with 0.09% sodium azide (liquid)

Substantial equivalence – performance characteristics

The Performance characteristics of the Cobas® Integra Reagent Cassette for Rheumatoid Factors II and the predicate device are compared in the table below.

Feature	Modified Device (Integra RF II)	Predicate Device (Integra RF)
Within-run precision (%CV)	1.1% at 50 IU/ml 1.0% at 80 IU/ml	1.6% at 32 IU/ml 1.4% at 125 IU/ml
Total precision (%CV)	6.8% at 50 IU/ml 4.4% at 80 IU/ml	8.5% at 32 IU/ml 5.4% at 125 IU/ml
Detection limit	1.25 IU/ ml	1.50 IU/ml
Hook Effect	> 3800 IU/ml	>12,600 IU/ml
Limitations	• Hemolysis – no significant interference • Icterus - no significant interference • Lipemia - no significant interference • Pathologically high levels of γ-globulin (25 g/L) decrease the apparent RF concentration	• Hemolysis – no significant interference • Icterus - no significant interference • Lipemia – triglyceride > 1500 mg/dl decrease apparent RF • Pathologically high levels of γ-globulin (24 g/L) decrease the apparent RF concentration
Method Comparison - Passing-Bablok Correlation	Integra 700 RF II / Integra 700 RF Y=0.89X + 8 IU/ml	Integra 700 RF / Cobas Mira Y=1.01X + 3 IU/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 5 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K000534
Trade Name: Integra Reagent Cassette for Rheumatoid Factors II
Regulatory Class: II
Product Code: DHR
Dated: February 15, 2000
Received: February 17, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K000534 N/A

Device Name: Cobas® Integra Reagent Cassette for Rheumatoid Factor II

Indications For Use: In vitro diagnostic reagent system intended for use on the Cobas® Integra 700 for the quantitative immunological determination of human rheumatoid factors in serum and plasma. Measurement of rheumatoid factor may be used as an aid in the diagnosis of rheumatoid arthritis.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Peter E Maksem

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000534